DEPARTMENT OF HEALTH AND HUMAN SERVICES

952034

Food and Drug Administration
New Orleans District
Nashville Branch Office
297 Plus Park Blvd.
Nashville, TN 37217

Telephone: 615-781-5380
Facsimile: 615-781-5391

February 15, 2005

Warning Letter No. 2005-NOL-11

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Chris E. Whitaker, Chief Member
Two Rivers LLC
3199 Highway 25 East
New Tazewell, Tennessee 37879

Dear Mr. Whitaker:

On January 11, 2005, an investigator from the Food and Drug Administration (FDA) conducted an inspection of your facility, Two Rivers LLC, 3199 Highway 25 East, New Tazewell, Tennessee 37879. This inspection determined your firm to manufacture electrically powered lift chairs. This product is a medical device under the Federal Food, Drug, and Cosmetic Act (the Act), because it is intended for use in diagnosing or treating a medical condition or to affect the structure or a function of the body (section 201(h) of the Act). You can find the Act and the *Code of Federal Regulation* (CFR) through links in FDA's home page at http://www.fda.gov.

The above-stated inspection revealed the devices to be adulterated within the meaning of section 501(h) of the Act [21 USC 351(h)] in that the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation, as specified in 21 CFR 820. Specific QS violations include:

1. Failure to establish procedures for quality audits and conduct such audits to assure the quality system is in compliance with the established quality system requirements, as required by 21 CFR 820.22.

2. Failure to establish and maintain procedures to control the design of the device in order to ensure specified design requirements are met, as required by 21 CFR 820.30(a). Specifically, your firm has no written procedures for design controls of the lift chair.

3. Failure to establish and maintain document control procedures, as required by 21 CFR 820.40. Specifically, your firm has no written procedures for making changes to documentation and changes made are not always documented. For example, the lift chair hand control change did not go through a formal change control or approval process.

4. Failure to establish and maintain procedures for finished device acceptance to ensure each production run, lot, or batch of finished devices meets acceptance criteria, as required by 21 CFR 820.80(d). Specifically, your firm has no written procedures for testing/evaluation or approval to distribute the finished lift chair.

5. Failure to establish and maintain procedures for acceptance of incoming product, as required by 820.80(b). Specifically, your firm has no written procedures for evaluation/acceptance of components and records are not maintained of the testing/evaluation or acceptance of the components.

6. Failure to establish and maintain procedures to control product not conforming to specified requirements, as required by 21 CFR 820.90(a). Specifically, your firm has no written procedures for handling non-conforming materials and records are not maintained of all non-conforming materials. For example, lift chair hand control failures and actions taken were not documented.

7. Failure to establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a). Specifically, your firm has no written procedures for a corrective and preventive action program.

8. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). Specifically, your firm has no written procedures for handling complaints or Medical Device Reports (MDRs) and results of investigations performed for complaints received in 2004 were not documented.

9. Failure to include or refer to the location of all quality assurance procedures and specifications of the DMRs (Device Master Records), as required by 21 CFR 820.181(c). Specifically, your firm has no formal DMRs for the lift chairs.

10. Failure to include complete acceptance records to demonstrate the device is manufactured in accordance with the DMRs, as required by 21 CFR 820.184(d). Specifically, the DHRs (Device History Records) fail to include documentation of acceptance activity performance on the lift chairs.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by FDA and must also promptly initiate permanent corrective and preventive actions.

Federal agencies are advised of the issuance of all warning letters about devices so they may take this information into account when considering the award of contracts. Additionally, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, which may include the refused entry of your affected products until the corrections are completed.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure similar violations will not recur.

If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed. Your reply should be directed to the attention of Kimberly L. McMillan, Compliance Officer, 297 Plus Park Boulevard, Nashville, TN 37217. If you have any questions concerning the violations noted, please contact Ms. McMillan at (615) 781-5380 extension 138.

Sincerely,

H. Tyler Thornburg
Director, New Orleans District

Enclosures:
Form FDA 483
Quality System Regulation 21 CFR 820